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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/692,191	CIFRA ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds Draper	1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *126-164* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *126-164* is/are rejected.

7)☒ Claim(s) *127-128,139-141,152-154* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 126-164 are presented for examination.

Applicant's Amendment dated February 14, 2011 has been received and entered into the present application.

Claims 126-164 are newly added and under examination. Claims 24-28, 30-31, 33, 35, 105, 107-109, 115-117 and 122-124 are cancelled.

Applicant's arguments, filed February 14, 2011, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Objection to the Claims (New Grounds of Objection)

Claim 139 is objected to for reciting the limitation "for increasing elastin content a region of skin of a subject", which is grammatically awkward. Correction is required.

Claims 127 and 128 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim because claim 127 provides for the use of zinc carbonate as the zinc-containing component and claim 128 provides for the use of zinc citrate as the zinc-containing component. However, claim 126 from which each of claims 127 and 128 depend only provides for "carbonate" or "citrate", not "zinc carbonate" or "zinc citrate". Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 140 and 141 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim because claim 140 provides for the use of zinc carbonate as the zinc-containing component and claim 141 provides for the use of zinc citrate as the

zinc-containing component. However, claim 139 from which each of claims 140 and 141 depend only provides for "carbonate" or "citrate", not "zinc carbonate" or "zinc citrate". Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 153 and 154 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim because claim 153 provides for the use of zinc carbonate as the zinc-containing component and claim 154 provides for the use of zinc citrate as the zinc-containing component. However, claim 152 from which each of claims 153 and 154 depend only provides for "carbonate" or "citrate", not "zinc carbonate" or "zinc citrate". Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 152 is objected to for reciting the limitation “derived from any member of the group consisting of”, which is improper Markush construction. Proper Markush language should be presented as "selected from the group consisting of A, B and C". See MPEP §2173.05(h).

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 126-164 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, the specification and claims as originally filed fail to provide clear written description for the newly added limitation directed to "wherein zinc is present in the composition at a concentration that increases elastin without causing epidermal sloughing and irritation due to zinc" (claims 126 and 139) or "wherein said formulation comprises zinc at a concentration that increases elastin without causing epidermal sloughing and irritation due to zinc" (claim 152).

MPEP §2163 states, "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test of sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." Ralston Purina Co. v. Far-Mar-Co., Inc., 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))…Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Applicant refers to the caption to Fig.1D as providing written support for the newly added claim limitations to claims 126, 139 and 152. Note, however, that original Fig.1D as filed October 22, 2003 was superseded by replacement Fig.1D as filed April 23, 2004 and does not contain such a caption. Since

p.15, para.[52], provides an explanation of Fig.1 and the effects of topical treatment with zinc, this disclosure will be analyzed for providing support for Applicant's newly added claim limitation.

Applicant's instant specification at p.15, para.[52], states:

"Figure 1 depicts representative photomicrographs of murine skin sectioned and stained with Verhoeff Elastica stain after 21 days topical treatment with a) Base only ("blank"), b) 10 μM Zn++ ("Z low"), c) 1.0 mM Zn++ ("Z med"), or d) 100 mM Zn++ ("Z high") depicting increasing elastin levels. As the dose of Zn increases from zero (a) to low (b) to medium (c) to high (d) the length, density and thickness of the black elastic fibers increases significantly. At high dose, epidermal sloughing and irritation occurs, however. Lower doses afford the benefits without local signs of irritation. Overall, ionic zinc affords dose-dependant increases in the elastin content of skin after topical administration."

The disclosure that the "low dose" of zinc ion (i.e., 10 μM Zn^{2+}) and the "medium dose" of zinc ion (i.e., 1.0 mM Zn^{2+}) as the doses of zinc ion that increased elastin content after topical treatment but did not result in epidermal sloughing and irritation fails to provide clear written support to now broaden the claims to read upon any concentration of zinc ion or zinc-containing component that is effective to increase elastin without causing epidermal sloughing and irritation. The specific disclosure of two discrete concentrations (i.e., 10 μM Zn^{2+} or 1.0 mM Zn^{2+}) of zinc ion that are effective to increase elastin content in the topically treated skin without resulting in epidermal sloughing and irritation does not constitute clear support to then broaden the claims to read upon the use of any concentration of zinc ion or zinc-containing component that is effective to increase elastin without causing epidermal sloughing and irritation. This newly added limitation represents a clear broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported by the original disclosure and clearly circumscribes a concept that was not in Applicant's possession at the time of the invention. In addition, note that this disclosure also does not clearly attribute the "epidermal sloughing and irritation" directly and specifically to the zinc component. In fact, zinc was not the only

component administered, given that the topical solutions employed in the disclosed experiment were formulated with a particular moisturizer base, and, thus, there is no clear written basis to attribute the "epidermal sloughing and irritation" effect to the zinc component per se.

For completeness of the record, it is noted that Applicant discloses that, "For improving elastin or elasticity in the skin, a composition according to this invention contains one or more zinc-containing components in a total concentration of from about 1.0 picomolar (pM) to about 900 μM, preferably from about 100 to about 500 pM. The composition may be applied topically so as to provide an effective amount of zinc to the area where the effect is desired, and may be applied at varying intervals and over varying durations to achieve the desired degree of increase in elastin content." (p.12, para.[39]) Though such disclosure is noted, it remains that these disclosed concentrations of zinc to be topically applied to skin to increase the elastin content thereof are described simply as being effective for providing an increase in elastin content, but are not described as providing this claimed function of increasing elastin content while not causing epidermal sloughing and irritation. Thus, the disclosure of these ranges at p.12, para.[39], cannot constitute disclosure of these newly claimed amounts because they are not clearly disclosed as being functional to both increase elastin and not cause epidermal sloughing or irritation.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms of in haec verba) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concepts of "wherein zinc is present in the composition at a concentration that increases elastin without causing epidermal sloughing and irritation due to zinc" (claims 126 and 139) or "wherein said formulation comprises zinc at a concentration that increases elastin without causing epidermal sloughing and irritation due to zinc" (claim 152).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 126-128, 135-141, 148-154 and 161-164 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, the specification as originally filed fails to provide adequate written description for concentrations of zinc that increases elastin without causing epidermal sloughing and irritation due to zinc (claims 126, 139 and 152).

Applicant refers to the caption to Fig.1D as providing written description for the newly added claim limitations to claims 126, 139 and 152. Note, however, that original Fig.1D as filed October 22, 2003 was superseded by replacement Fig.1D as filed April 23, 2004 and does not contain such a caption. Since p.15, para.[52], provides an explanation of Fig.1 and the effects of topical treatment with zinc, this disclosure will be analyzed for providing description of Applicant's newly added claim limitation.

Applicant's instant specification at p.15, para.[52], states:

"Figure 1 depicts representative photomicrographs of murine skin sectioned and stained with Verhoeff Elastica stain after 21 days topical treatment with a) Base only ("blank"), b) 10 μM Zn++ ("Z

low"), c) 1.0 mM Zn++ ("Z med"), or d) 100 mM Zn++ ("Z high") depicting increasing elastin levels. As the dose of Zn increases from zero (a) to low (b) to medium (c) to high (d) the length, density and thickness of the black elastic fibers increases significantly. At high dose, epidermal sloughing and irritation occurs, however. Lower doses afford the benefits without local signs of irritation. Overall, ionic zinc affords dose-dependant increases in the elastin content of skin after topical administration."

Applicant further discloses that, "For improving elastin or elasticity in the skin, a composition according to this invention contains one or more zinc-containing components in a total concentration of from about 1.0 picomolar (pM) to about 900 μM, preferably from about 100 to about 500 pM. The composition may be applied topically so as to provide an effective amount of zinc to the area where the effect is desired, and may be applied at varying intervals and over varying durations to achieve the desired degree of increase in elastin content." (p.12, para.[39])

The disclosure that the "low dose" of zinc ion (i.e., 10 μM Zn^{2+}) and the "medium dose" of zinc ion (i.e., 1.0 mM Zn^{2+}) as the doses of zinc ion that increased elastin content after topical treatment but did not result in epidermal sloughing and irritation is noted, but fails to provide adequate written description of the entire genus of zinc concentrations that are effective to increase elastin content when applied topically without causing epidermal sloughing and irritation. Though Applicant provides a functional description of the concentrations to zinc to be administered (i.e., that it is effective to increase elastin content but does not cause epidermal sloughing or irritation due to zinc), Applicant has conspicuously failed to provide any description of the particular amounts, or range of amounts, that are actually functional to accomplish the effect as instantly claimed and would provide adequate written description of this claimed genus of amounts capable of increasing elastin in the absence of epidermal sloughing and irritation that Applicant was actually in possession of, and intended to be used within the context of the present invention, at the time of the invention, with the exception of the two experimentally determined concentrations of 10 μM Zn^{2+} and 1.0 mM Zn^{2+}.

Applicant's instant specification provides exemplary ranges of zinc concentrations that may be used for the purpose of increasing elastin and elasticity of the skin. See p.12, para.[39], wherein Applicant has disclosed the use of zinc in a concentration of from about 1.0 picomolar (pM) to about 900 μM, preferably from about 100 to about 500 pM, for increasing elastin and elasticity of the skin. However, though such disclosure of these ranges has been noted, there is no express disclosure or indication that said ranges are effective to not only provide an increase in elastin content of the skin, but are also effective to provide this elastin-promoting effective in the absence of epidermal sloughing or irritation. As a result, the disclosure of these broader zinc concentration ranges of from about 1.0 picomolar (pM) to about 900 μM, preferably from about 100 to about 500 pM, fails to constitute a disclosure of amounts that are germane to achieving the instantly claimed function. Accordingly, the instant specification appears to lack any specific description of the amounts that would fall within the instantly claimed genus of concentrations effective for the claimed function such that these concentrations could be immediately envisaged and/or readily identified, except for the two concentrations disclosed (i.e., 10 μM Zn^{2+} and 1.0 mM Zn^{2+}). Absent such description, one of skill in the art would have to undertake hit or miss testing to determine the full scope of the genus, which is clearly indicative of the fact that Applicant was, in fact, not in possession of the full scope of concentrations effective to achieve the instantly claimed function(s). This is because Applicant cannot logically be in possession of that which he has yet to identify.

Absent a clear description of the concentrations that are effective to achieve the function(s) instantly claimed, it remains that Applicant has failed to clearly define the metes and bounds of the claimed genus of concentrations. While it is duly noted that the claimed genus is limited to those concentrations capable of functioning in the claimed manner, it remains that Applicant has not appropriately defined the metes and bounds of the genus even when limited by function. The specification provides no disclosure beyond the generic disclosure of the required function that would correlate a particular concentration to performance of the claimed function that would be readily

identifiable to one of skill in the art. Further, Applicant has failed to establish on the record that the state of the art was sufficiently well-developed that one of ordinary skill in the art at the time of the invention would have immediately envisaged the specific concentrations that would perform the claimed function(s) in the instant specification. In other words, the present specification fails to provide disclosure beyond the generic disclosure of the required functions and two specific concentrations thereof (i.e., 10 μM Zn^{2+} and 1.0 mM Zn^{2+}) that would provide a means for identifying the concentrations of zinc that would have been amenable for use in the present invention, absent factual evidence to the contrary. Furthermore, it has been held that a wish or plan for obtaining the invention as claimed does not provide adequate written description of the invention. See, e.g., Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004).

While it is recognized that adequate written description of a limitation is not required to be stated in haec verba in the specification or claims as originally filed, adequate written support for claim limitations must arise from either an explicit or implicit suggestion by the disclosure to show that such a concept as claimed was actually in possession of Applicant at the time of the invention. For the reasons provided supra, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of concentrations of zinc that increases elastin without causing epidermal sloughing and irritation due to zinc (claims 126, 139 and 152).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 126-164 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Each of independent claims 126, 139 and 152 recite that "zinc is present in the composition at a concentration that increases elastin without causing epidermal sloughing and irritation due to zinc" (see, e.g., l.15-16 of claims 126; l.4-5 of claims 139; and l.4-6 of claim 152). However, the antecedent basis for the term "zinc" as used in this limitation renders the claims indefinite because it is unclear if the claimed "concentration" of zinc is intended to be a concentration of "zinc" ion or a concentration of "zinc-containing component (as provided for in claims 126 and 139) or a concentration of "zinc-comprising formulation". The claims that depend from claims 126, 139 and 152 fail to correct this ambiguity in the claims and, thus, are deficient for the same reasons. As a result of this ambiguity in the claims, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the metes and bounds of the subject matter for which Applicant is presently seeking protection. Clarification is required.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claims 126-138 and 152-164 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The provision that the claimed zinc composition is topically applied to a region of skin "in an elastin-increasing effective amount" as recited in instant claim 126, wherein the zinc "is present in the composition at a concentration that increases elastin without causing epidermal sloughing and irritation

due to zinc" renders the claim indefinite because it is unclear if the amount of zinc to be administered is one that is (1) effective for increasing elastin or (2) effective for increasing elastin without causing epidermal sloughing and irritation. Note, further, that the instant specification clearly supports the position that the two amounts (i.e., (1) effective for increasing elastin or (2) effective for increasing elastin without causing epidermal sloughing and irritation) are not co-extensive. See, e.g., p.15, para.[52], of the instant specification, which describes an experimental study using varying concentrations of Zn^{2+} (i.e., (a) base only; (b) 10 μM Zn^{2+}; (c) 1.0 mM Zn^{2+}; and (d) 100 mM Zn^{2+}), wherein an increase in elastin content was observed using each zinc concentration, but at the highest dose, epidermal sloughing and irritation was observed. Thus, a concentration such as, e.g., 100 mM Zn^{2+} is clearly an "elastin-increasing effective amount", but it not a concentration of zinc that increases elastin without causing epidermal sloughing and irritation due to zinc. Accordingly, it is unclear which amount of zinc is actually intended to limit the instant claims. Clarification is required.

Analogously, the provision that the claimed zinc composition is topically applied to an area of skin in a "therapeutically effective amount" as recited in instant claim 152, wherein the formulation "comprises zinc at a concentration that increases elastin without causing epidermal sloughing an irritation due to zinc" renders the claim indefinite because it is unclear if the amount of zinc to be administered is one that is (1) therapeutically effective, which is understood to be specifically therapeutically effective for achieving the claimed objective, i.e., increasing elastin, or (2) effective for increasing elastin without causing epidermal sloughing and irritation. As above, the instant specification clearly supports the position that the two amounts (i.e., (1) effective for increasing elastin or (2) effective for increasing elastin without causing epidermal sloughing and irritation) are not co-extensive. See, e.g., p.15, para.[52], of the instant specification, which describes an experimental study using varying concentrations of Zn^{2+} (i.e., (a) base only; (b) 10 μM Zn^{2+}; (c) 1.0 mM Zn^{2+}; and (d) 100 mM Zn^{2+}), wherein an increase in elastin content was observed using each zinc concentration, but at the highest dose, epidermal sloughing

and irritation was observed. Thus, a concentration such as, e.g., 100 mM Zn^{2+} is clearly a "therapeutically effective amount" for increasing elastin, but it not a concentration of zinc that increases elastin without causing epidermal sloughing and irritation due to zinc. Accordingly, it is unclear which amount of zinc is actually intended to limit the instant claims. Clarification is required.

As a result of this ambiguity in the claims, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the metes and bounds of subject matter for which Applicant is presently seeking protection.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claims 126, 129, 132, 135, 136, 138, 139, 142, 145, 148, 149, 152, 155, 158, 161, 162 and 164 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant defines the composition for application in each of claims 126 and 139 as a composition comprising "one or more zinc-containing components", wherein the "one or more zinc-containing components" is selected from, inter alia, zinc acetate, ascorbate, aspartate etc. However, the only "zinc-containing components" provided for in the extensive list of components are zinc acetate, zinc amino acid complexes and zinc nucleotide complexes. The other options named in the list of possible components do not comprise zinc and, thus, it is unclear how they could be employed as a "zinc-containing component" to provide zinc as part of the claimed composition. Clarification is required.

Similarly, Applicant defines the composition for application in claim 152 as a "zinc-comprising formulation", wherein the zinc "is derived from any member of the group consisting of", inter alia, zinc acetate, ascorbate, aspartate, etc. However, the only zinc-containing compounds provided for in the extensive list of compounds for use in the formulation are, inter alia, zinc acetate, zinc amino acid

complexes and zinc nucleotide complexes. The other options named in the list of possible compounds do not comprise zinc and, thus, it is unclear how they could be employed for the purpose of providing zinc as part of the claimed composition. Clarification is required.

As a result of these ambiguities in the claims, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the metes and bounds of the subject matter for which Applicant is presently seeking protection.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claims 135 and 148 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The application of the zinc-containing composition as provided for in each of instant claims 135 and 148 to a "site on the skin of the subject" renders the claims indefinite because it is unclear if this "site on the skin of the subject" to be treated is, in fact, the same area of skin defined in the preamble objective of the method as the "region of skin" to which the zinc composition is applied and in which the elastin content is increased as a result of application of the zinc composition. Clarification is required. As a result of this ambiguity in the claim, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the metes and bounds of the subject matter for which Applicant is presently seeking protection.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 126, 128-131, 135-139, 141-144, 148-150, 152, 154-157 and 161-164 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus (U.S. Patent No. 6,573,299; Issued June 2003, Filed September 1999), citing to STN Registry File No. 546-46-3 as evidence, in view of Uitto ("Connective Tissue Biochemistry of the Aging Dermis. Age-Related Alterations in Collagen and Elastin", Dermatol Clin, 1986 Jul; 4(3):433-436; Abstract Only).

Petrus teaches a method for the treatment of orbital disorders associated with the aging eye, including the improvement of age-related changes to the eyelids, such as dry skin or wrinkles (col.2, l.22-24), by applying a topical composition comprising a penetration enhancer and one or more bio-affecting agents (col.2 l.24-28), such as zinc citrate (col.13, l.21-28, especially col.13, l.25), wherein the bio-affecting agent penetrates the underlying tissue into the vascular network of the orbit via application to the eyelid surface (i.e., meets Applicant's limitation of applying the composition to the face or the furrows or wrinkles of the face as recited in present claims 26 and 107). Petrus further teaches that the

composition may also include emollients (i.e., meets Applicant's limitation of a "moisturizer" as recited in present claims 33 and 114; col.14, l.20-24), provided that the inclusion of such an additive does not defeat the objective of the invention (col.14, l.34-35). Petrus further teaches that the concentration of the bio-affecting agent will vary from about 0.1-40% of the total composition (col.6, l.60-62) and can also vary greatly and will be dependent upon many factors, e.g., type, bioavailability, potency, surface area to which it is applied, composition used and the amount of the penetrating agent used (col.6, l.56-60). Note that, for example, if one were to use 0.1% concentration of active agent as disclosed by Petrus at col.6, l.60-62, then 0.1% zinc citrate=0.1g zinc citrate/100 ml of composition; (0.1g zinc citrate/100 ml of composition)*(1mol/574 g/mol)*(1000 ml/L) = 0.0017 M = 1.7 mM = 1700 μM (see STN Registry File No. 546-46-3 for molecular formula of zinc citrate). This meets Applicant's claimed concentration ranges of "about 1.0 pM to about 900 μM" (see, e.g., instant claims 129-131, 142-144 and 155-157) because, though the value falls outside the exact numerical range, Applicant has defined the range using the term "about" and, thus, this concentration is still considered to meet the claimed concentration in the absence of an express definition of the term "about" and the degree of variance tolerated, and intended to be conveyed, by the term.

Regarding the use of the transitional phrase "consisting essentially of" (claim 126), the MPEP states at §2111.03, "The transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basis and novel characteristic(s)' of the claimed invention…For the purposes of searching for and applying prior art under 35 U.S.C. §102 and §103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to 'comprising'."

Applicant has failed to definitively point out the basic and novel characteristics of the invention. However, taken in its broadest, reasonable interpretation, the basic and novel characteristic of the presently claimed invention must necessarily lie in the fact that the composition must retain efficacy in

effecting the increase in elastin content of the tissue to which it is applied. For this reason, the inclusion of any additional elements or steps that affect the function of the claimed active agent (i.e., zinc citrate) would necessarily be excluded from the claimed invention.

If the composition must retain efficacy in effecting the increase in elastin content of the tissue to which it is applied, then the fact that Petrus explicitly teaches the inclusion of additives, such as emollients, that do not defeat the objective of the invention (col.14, l.34-35) is clear evidence that the disclosed additional additive agents are not patentably excluded from the claim language, absent factual evidence to the contrary, because they do not affect the characteristics or properties of the composition taught by the reference.

Though Petrus does not explicitly teach that the application of the disclosed zinc citrate composition effects an increase in the elastin content of the tissue to which it is applied, it is noted that the very administration of the same compound(s) as claimed (i.e., zinc citrate, optionally in combination with a moisturizing compound) topically to the skin of a subject is considered to necessarily have the claimed effect on increasing the elastin content of said tissue, whether recognized by the patentee or not. Products of identical chemical composition cannot exert mutually exclusive properties when administered under the same circumstances or, in the present case, the same host. In other words, a composition and its effects are inseparable. Please reference MPEP §2112.

The explanation of an effect obtained when using a compound cannot confer novelty and/or non-obviousness on a known process if the skilled artisan was already aware of the occurrence of the desired therapeutic effect. In other words, even if the effect of increasing elastin content of a tissue to which the zinc composition had been applied was not itself recognized as a pharmacological effect of topically applying the claimed zinc citrate composition of Petrus to a patient, such an effect is not considered a new therapeutic application because the known treatment of skin using such a compound was already known and recognized in the prior art. Though mechanisms of action or new properties of a compound are no

doubt important contributions to scientific and pharmaceutical development, the assessment of patentability under 35 U.S.C. 102 and/or 35 U.S.C. 103 is based upon the therapeutic applications and effects of the compounds, not the mechanisms and/or properties by which they exert such a therapeutic effect.

The teaching of Petrus to apply the disclosed zinc-containing composition directly to the skin for the improvement of age-related changes to the eyelids, such as dry skin or wrinkles (col.2, l.22-24), necessarily meets Applicant's claimed limitation to the application of the claimed composition to tissue in need of increased elastin content because, as Uitto ("Connective Tissue Biochemistry of the Aging Dermis. Age-Related Alterations in Collagen and Elastin", Dermatol Clin, 1986 Jul; 4(3):433-436; Abstract Only) teaches, perturbations in the supramolecular organization of the elastic fiber network as occur with cutaneous aging lead to alterations in the mechanical properties of the skin, as manifested by loose and sagging skin with reduced resilience and elasticity (abstract). In view of such a teaching, the application of the disclosed zinc composition of Petrus to improve the dry and/or wrinkled skin around the eyes is necessarily an area in "need of increased elastin content", whether recognized by the patentee or not, since dry and/or wrinkled skin is necessarily in need of increased elastin to improve elasticity and ameliorate the looseness and sagging of the dry and/or wrinkled skin.

Regarding the claimed dosage amounts of the zinc citrate compound, note that Petrus clearly teaches amounts of zinc citrate that overlap with the amounts instantly claimed (see, supra, the calculations regarding the amount of the disclosed bio-affecting agent, zinc citrate). In addition, Petrus expressly teaches that, "The concentration of the bio-affecting agents in the composition can also vary greatly and will be dependent upon many factors, e.g., type, bioavailability, potency, surface area to which it is applied, composition used and the amount of the penetrating agent used" (col.6, l.56-60). It is obvious from the above teachings that Petrus expressly contemplates variation in the dosage amounts and schedule of the active agent and acknowledges that such a determination would be made in accordance

with a variety of factors, each of which would have reasonably commended themselves to one of ordinary skill in the art at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan. Factors that would have been taken into consideration when making such a determination would have included, but would not have been limited to, the age, weight, sex, diet and medical condition of the patient, severity of the disease, route of administration, pharmacological considerations, e.g., activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage regimen that would have actually been employed would have been expected to vary widely and, in the absence of evidence to the contrary, would not have been inconsistent with that which is presently claimed.

In addition, the concentration of the active ingredient is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum of workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s). MPEP §2144.05.

Response to Applicant's Arguments

Applicant states that the instant claims are patentable over U.S. Patent No. 6,573,299 to Petrus and further argues that Applicant's product continues to win industry accolades, which is allegedly evidence of nonobviousness.

Firstly, Applicant argues against the application to Petrus, stating that Petrus fails to teach or suggest all of the features in the pending claims. Applicant's argument has been fully considered, but fails to be persuasive in view of the extensive reasons provided supra as to why Petrus in view of Uitto render the instant claims obvious. Applicant's attention is directed thereto.

Secondly, Applicant argues that the instant product continues to win industry accolades and alleges this is evidence of nonobviousness. Applicant's remarks have been fully and carefully considered, but fail to be persuasive for the following reasons: (1) Applicant once again has failed to describe the specific product formulation that, in fact, has received such recognition and diffusely references "Applicant's commercial product", which fails to point out the specific formulation and how this product relates to the invention as instantly claimed and (2) the fact that a product allegedly covered by the instant claims has been generally received more favorably by consumers than other comparable products does not, without more, support non-obviousness of the invention. Should Applicant be attempting to rely upon evidence of commercial success as indicia of non-obviousness of the claimed invention, Applicant is directed to MPEP §716.03, which requires Applicant to show, inter alia, a nexus between the claimed invention and evidence of commercial success, that the evidence of commercial success in, in fact, commensurate in scope with the claimed subject matter, and that commercial success must flow from the functions and advantages disclosed or inherent in the specification description. Though Applicant asserts that the performance of this commercial product "can be directly attributed to the benefits obtained by practicing the presently claimed invention", this is no more than an allegation of Counsel and does not replace the need for evidence that the commercial success flows from the disclosed functions and advantages described in the accompanying specification. Moreover, Applicant conspicuously fails to address the conditions of this alleged "test" used by Allure Magazine to determine what they consider to be the "best beauty products". There is no description of, for example, the selection criteria, frequency of use, whether the products were used as directed, the number of people that tested each product, etc. Thus, there is no supporting evidence that these "awards" have any scientific merit to rise to the level of evidence supportive of commercial success. As a result, though Applicant's statements regarding industry recognition are noted, they are unpersuasive in establishing non-obviousness of the instantly claimed invention over the cited prior art.

Conclusion

Rejection of claims 126-164 is proper.

No claims of the present application are allowed.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP §714.02 and §2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, not the published application. Due to the procedure outlined in MPEP §2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. §102 or 35 U.S.C. §103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims and share an inventor or assignee with the instant application. A copy of such copending claims is requested in response to this Office action in order to assist the examiner with double patenting analysis in the application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds Draper whose telephone number is (571)272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S. Lundgren can be reached on (571)-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds Draper/
Primary Examiner, Art Unit 1629

April 14, 2011